

REMARKS

Claims 1, 5, 27 and 28 are currently amended. Claim 30 is canceled. Entry of this amendment is appropriate because it places the case in better condition for appeal and simplifies issues for appeal. Reconsideration is urged.

I: Interview Summary

On March 24, 2009, Applicants' attorney Michael Krenicky telephone Examiner Nguyen regarding the outstanding written description rejection in the above-referenced case.

No prior art references were discussed.

No exhibits were shared, and no demonstrations were conducted.

Claim 1 was discussed generally. Mr. Krenicky explained to the Examiner the presently claimed numbers were supported since they were in a range. Mr. Krenicky proposed amending claims 1, 27 and 28 back to the previously claimed numbers, and that the previous numbers were clear.

No agreements were made between Mr. Krenicky and Examiner Nguyen in the interview.

II: The rejection of claims 1-9, 11-13, 17, 19, 21, 23 and 27-30 under 35 U.S.C. 112, 1st paragraph.

Independent claims 1, 27 and 28 are currently amended. Applicants further submit that these claims are clear. For example, even if the elements (a) and (b) or (b) and (c) of claim 1 overlapped, then a larger percentage would be required to satisfy the claim. The claim is clear to one of skill in the art. Reconsideration is urged.

Claim 29 was rejected under 35 U.S.C. 112 as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicants traverse the Examiner's rejection that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed had possession of the claimed invention. The Office, without any scientific evidence or reasoning, alleges that "a first polyethylene glycol having a first average molecular weight, a second polyethylene glycol having a second average molecular weight, and a third

polyethylene glycol having a third average molecular weight" were not in Applicants possession. Applicants traverse this rejection for the following reasons. Reconsideration is urged for the reasons below:

It is well settled that a specification complies with the written description requirement if it provides "a precise definition, such as by structure, formula, chemical name, or physical properties of the claimed subject matter sufficient to distinguish it from other materials." See, e.g., *University of California v. Eli Lilly and Co.*, 43 U.S.P.Q.2d 1398, 1404 (Fed. Cir. 1997); *Enzo Biochem v. Gen-Probe Inc.*, 63 U.S.P.Q.2d 1609, 1613 (Fed. Cir. 2002).

Under this standard, the Examiner's conclusion that the specification requires more than the present disclosure is plainly incorrect. The specification discloses, and one skilled in the art would clearly recognize, that the scope of the present invention includes a first polyethylene glycol having a first average molecular weight, a second polyethylene glycol having a second average molecular weight, and a third polyethylene glycol having a third average molecular weight in accordance with claim 29.

Applicants submit that the specification provides adequate written description of the claimed invention. Claim 29 is directed to a granule in accordance with claim 28, wherein the synthetic polymer wax composition is an admixture of a first polyethylene glycol having a first average molecular weight, a second polyethylene glycol having a second average molecular weight, and a third polyethylene glycol having a third average molecular weight. The specification defines a wide molecular weight distribution on page 3, and further explains the molecular weight of wax on page 11. Page 11 further explains that "the wax composition comprising a wide molecular weight distribution may in particular be obtained by mixing two or more wax compositions having different average molecular weight . . ." Moreover, Example 1, shows PEG admixtures P1 to P7. More specifically, P6 is provided, which for example, also has the requisite wide molecular weight distribution required by claim 28. Admixtures of a first, second, third, fourth and fifth PEG are provided in a single sample, *i.e.*, P6. The description need not be in the same words as the claim language to provide adequate written description support under 35 U.S.C. 112 (*i.e.*, "ipsis verbis") (*Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972)).

At least samples P4, P5, P6 and P7 in Example 1 show the selection of the synthetic polymer wax composition as an admixture of at least a first polyethylene glycol

having a first average molecular weight, a second polyethylene glycol having a second average molecular weight, and a third polyethylene glycol having a third average molecular weight. The claimed admixture is clearly envisioned by an artisan once apprised of Applicants' invention.

Notwithstanding the above, the Examiner has not provided sufficient evidence or reasoning to rebut that the specification provides an adequate written description for the claimed admixture. In this regard, additional representative species are not required to be disclosed. Given the high degree of relatedness recited in the claims, an extremely high degree of predictability exists as to the structure and function of the PEG admixtures falling within the claims.

It is settled case law that the exact words of a claim need not appear in the specification in order for that specification to satisfy the description requirement of Section 112. See *In re Wright*, 9 USPQ 24, 1649, 1651, CAFC, 1989 for a case right on point. One skilled in the art would clearly recognize from the specification that embodiments of the invention include various admixtures. See also, the specification at page 5, lines 22-26, where it describes two or more wax compositions comprising narrow molecular weight distributions-- accordingly such are suitable for use in accordance with the present disclosure. Accordingly, claim language claiming synthetic polymer wax composition as an admixture of a first polyethylene glycol having a first average molecular weight, a second polyethylene glycol having a second average molecular weight, and a third polyethylene glycol having a third average molecular weight is appropriate and not new matter. Reconsideration of claim 29 is urged.

Therefore, Applicants respectfully submit that the specification contains a sufficient description of the structural and functional characteristics of the claimed admixture to fulfill the requirements of 35 U.S.C. 112. Reconsideration and withdrawal of the rejection are therefore respectfully requested.

III. The Rejections under 35 U.S.C. 103

The present disclosure relates to a granule including a core and a coating wherein the core includes an active compound and the coating includes a synthetic polymer wax composition with a wide molecular weight distribution. The specification explains on page 2 that Applicants found that coating of particles, including active compounds, with a wax composition including a wide molecular weight distribution improves Heubach dust figures of the coated finished granules significantly compared to ordinary granules

typically coated with a wax composition including a narrow molecular weight distribution. Moreover, Applicants explain on page 2 that they have found that by using a wax composition comprising a wide molecular weight distribution in the coating, the coating becomes more elastic compared to granules coated with a wax composition comprising a narrow molecular weight distribution. Applicants clearly define the term wide molecular weight distribution on page 3 and explain how it is different than typical narrow molecular weight distribution. Applicants further provided examples showing the skilled artisan the superior benefits of providing a coating with the wide molecular weight distributions.

Claim 1, refers to, *inter alia*, a granule comprising a core and a coating wherein the core comprises an active compound and the coating comprises a synthetic polymer wax composition, wherein the synthetic polymer wax composition is characterized as having a specified wide molecular weight distribution. Independent claims 27 and 28 also claim a wide molecular weight distribution.

Iijima relates to a product obtained by granulating an enzyme powder. The Iijima method produces granules of raw enzyme powder by admixing the enzyme powder with polyethylene glycol or polyoxyethylene-polyoxypropylene block polymer of specific quality as a binder and granulating by agitating the resulting combination at a temperature not lower than the melting point of the binder. The Iijima method is suitable for production of enzyme-containing granules for use in detergents, medicines, etc.

The Examiner has failed to make a *prima facie* showing of obviousness because Iijima reference is deficient and does not show the requisite wide molecular weight distribution of Claims 1, 27 and 28. Nowhere is a molecular weight distribution described. Conversely, the Examiner cites to Col. 6 and Col. 7 to show that Iijima shows mixtures of PEG. Applicants submit the reference does not show that possession of the wide molecular weight distribution of independent claims 1, 27 and 28.

Applicants direct the Examiner's attention to Example 1 of the Applicants' disclosure. Here Applicants show not only mixtures of PEG with various molecular weights, but Applicants demonstrate the importance of a wide molecular weight distribution. Sample P1 included a mixture of PEG-400 (10%) and PEG-4000 (90%). While Example P1 is relates to a mixture of PEG, it is deficient in that lacks the wide molecular weight distribution, as claimed. Still referring to Example 1 of Applicants disclosure, Examples P4 to P7 not only contain PEG of varying average molecular weight, but also the requisite wide molecular weight distribution. Example 1 clearly demonstrates that Applicants disclosure of

a wide molecular weight distribution is superior to a mere mixture of PEG. One of skill in the art would not gain this understanding based on the disclosure of Iijima.

Accordingly, Applicants submit that Iijima fails to teach each and every element of Claims 1, 27 and 28, and the Applicants example highlights this unexpected and unanticipated discovery. As the Examiner has failed to make a prima facie case of obviousness, Claims 1, 27 and 28 are not obvious.

Applicants further note that Iijima relates generally to products obtained from granulating an enzyme powder. The Examiner has not provided any reason to alter the Iijima reference. At most, the PEG mixtures proposed by the Examiner may offer an invitation to do experiments with enzyme granules and PEG mixtures.

A patent claim is obvious when "the prior art would have suggested to one of ordinary skill in the art that [the claimed invention] should be carried out and would have a reasonable likelihood of success... . Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure." *In re Dow Chemical*, 837 F.2d 469, 473 (Fed. Cir. 1988); see also, 35 U.S.C. § 103. An invitation to experiment, alone, cannot make an invention obvious. *In re Dow*, 837 F.2d at 473.

Applicants believe there is no evidence given in Iijima that providing a mixture of PEG would necessarily mean providing a wide molecular weight distribution as described herein. A skilled person in the art would have no reasonable expectation of success that any PEG mixture could be used to solve the problems of the present disclosure. Even if it was obvious to try to experiment it is not necessarily true that there would be any reasonable expectation of success. In the present case, a reasonable expectation of success requires that the skilled person can predict that any PEG mixture having the specified wide molecular weight distribution would solve the problems of the present disclosure.

Applicants direct the Examiner's attention to example 2 of Applicants' disclosure. Example 2 shows a significant reduction of dust levels by example P6 having a wide molecular weight distribution. Even if there were motivation to try PEG mixtures having wide molecular weight distributions as a coating (which Applicants do not concede is proper), there was no reasonable expectation of success because it was not predictable whether such coatings as claimed would work at all. At best, some reduction in dust could be hoped for, possibly making it worth a try. However, an invitation to experiment cannot make an invention obvious. *Dow*, 837 F.2d at 473. Applicants have made a

contribution to the art and have showed significant results for reduction of dust levels and using coatings with a wide molecular weight distribution.

Applicants further note that the Examiner has not provided a sufficient reason or explicit analysis of why the Ijima reference should be applied. The cited reference is devoid of any suggestion of having a wide molecular weight distribution, as advanced by the Examiner, except from using Applicants' disclosure as a template through hindsight reconstruction of Applicants claim. Thus, the Examiner has erroneously retraced the path of the inventor with hindsight –discounting the number of complexities of the alternatives in order to conclude that the specifically claimed composition was obvious. This reasoning is always inappropriate for an obviousness test based on the language of Title 35 that requires the analysis to examine "the subject matter as a whole" to ascertain if it "would have been obvious at the time the invention was made." 35 U.S.C. § 103(a).

Applying a non-rigid TSM analysis, one of ordinary skill in the art would not be motivated by Ijima to modify the PEG mixtures of Iijima, to somehow arrive at the Applicants claimed invention having the requisite wide molecular weight distribution.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103. Applicants respectfully request reconsideration and withdrawal of the rejection.

IV. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

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